

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
<i>ex rel.</i> LESLIE STEURY, <i>et al.</i> ,	§	
	§	
Plaintiffs,	§	Civil Action No. H-07-1705
	§	Judge Vanessa Gilmore
vs.	§	
	§	
CARDINAL HEALTH, INC., <i>et al.</i> ,	§	
	§	
Defendants.	§	

AMENDED MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

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I. SUMMARY OF ARGUMENT

Plaintiff Leslie Steury (“Steury”) has filed a *qui tam* action on behalf of the United States, seventeen States, and the District of Columbia, alleging violations of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, and parallel state false claims statutes. Steury’s First Amended Complaint names three defendants: Cardinal Health, Inc., Cardinal Health 303, Inc., and Cardinal Health Solutions, Inc. (collectively, “Cardinal”),¹ that allegedly manufactured and sold a medical device known as an infusion pump. Steury’s action must be dismissed because it is fatally flawed as a matter of law on several bases.

First, the purpose of the FCA is to reward private parties (referred to as “relators”) who uncover fraud against the federal government. The statute does not reward relators who attempt to seek an undeserved bounty by alleging “fraud” based on conduct already known to the government. Thus, under the terms of the FCA, a court cannot exercise subject matter jurisdiction when the allegations raised by the relator are based on a prior public disclosure of that information and the relator is not the “original source” of that information.

Here, Steury alleges that Cardinal either submitted, or “caused” the submission of, false claims by selling infusion pumps that were allegedly defective. As alleged by Steury, the infusion pump was regulated by the Food and Drug Administration (“FDA”). Moreover, the alleged “defect” in the infusion pump was disclosed by Cardinal on the FDA’s publicly-accessible Internet website several years before Steury commenced this lawsuit, and reports on the FDA’s website indicate that, contrary to Steury’s allegation, the infusion pump was not

¹ To clarify the identities of the three defendants, Cardinal Health, Inc. is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal Health, Inc. does not manufacture, sell or distribute infusion pumps. Cardinal Health 303, Inc. and Cardinal Health Solutions, Inc., both Delaware corporations with a principal place of business in San Diego, California, are involved in the manufacture, sale and distribution of infusion pumps. Although one of the three defendants was improperly joined in this action, and that objection is reserved, the focus of this motion is on Steury’s flawed theories of recovery that fail to state a claim against any of the defendants.

defective. Furthermore, Steury does not qualify as the original source of information regarding the alleged “defect” because she admits that she learned that information second hand. Accordingly, this Court cannot properly exercise subject matter jurisdiction over any of the claims asserted by Steury in this action. Steury should not be permitted to seek an undeserved bounty based on a parasitic lawsuit that feeds on previously disclosed public information.

Second, the FCA is intended as a remedy for “knowingly” false claims intended to defraud the government. It is not a vehicle to seek redress for an alleged breach of contract or regulatory non-compliance. Steury’s assertion that the infusion pump was allegedly “defective” amounts to nothing more than an alleged breach of contract or alleged non-compliance with FDA regulations. The FDA’s administrative review process, not the federal courts, is the appropriate forum for addressing Steury’s claim regarding an allegedly defective medical device. Cardinal’s voluntary disclosures to the FDA of incidents involving the infusion pump – disclosures that were published on the FDA’s publicly-accessible Internet website years before Steury filed this lawsuit – demonstrate the FDA’s regulatory authority relating to this matter and negate any inference that Cardinal could have knowingly concealed the alleged “defect” in the infusion pump. The alleged claims were not even false, let alone knowingly false.

Third, Steury’s claims are based on the theory that Cardinal made false “certifications” to the government regarding the performance of the infusion pumps. However, a certification is not actionable under the FCA unless the certification is knowingly false and the government’s payment is conditioned on the certification. Here, there were no false certifications and, in any event, the government’s payment was not conditioned on any certification regarding the performance of the pumps. Thus, there could be no violation of the FCA.

Fourth, Steury's Complaint is based on assertions of law, made on information and belief, and lacking critical allegations of fact. Steury fails to identify any federally-owned hospital that purportedly purchased an infusion pump based on allegedly false claims made by Cardinal. Moreover, Steury fails to identify any payment made by any federal or state health care program to a hospital for the use of an infusion pump based on a false claim allegedly "caused" by Cardinal. In addition, Steury fails to identify any false record made or used by Cardinal, fails to identify any "reverse" false claim made by Cardinal, and fails to identify any conspiracy to submit false claims. In short, Steury's Complaint lacks the basic ingredients to allege a viable claim under the FCA. The Complaint is not pled with particularity pursuant to Rule 9(b) and it fails to state a claim pursuant to Rule 12(b)(6).

For these and other reasons discussed in more detail below, Steury's action must be dismissed with prejudice as a matter of law.

II. STANDARD OF REVIEW

When a motion to dismiss for lack of subject matter jurisdiction is filed under Rule 12(b)(1), and the defendant proffers evidence demonstrating a lack of jurisdiction, the burden is on the plaintiff to establish that the Court may properly exercise jurisdiction. Fed. R. Civ. P. 12(b)(1); *Morris v. Dep't of Justice*, 540 F. Supp. 898, 900-01 (S.D. Tex. 1982), *aff'd*, 696 F.2d 994 (5th Cir.), *cert. denied*, 460 U.S. 1093 (1983). The Court is not limited to evaluating subject matter jurisdiction based on the allegations in a complaint, but rather, is permitted to consider evidence relating to whether the Court may exercise jurisdiction. *See id.*; *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir.), *cert. denied*, 454 U.S. 897 (1981). In particular, the Court may take judicial notice of documents in the public domain, such as filings with administrative agencies. *In re CNET Networks, Inc.*, 483 F. Supp. 2d 947, 953-54 (N.D. Cal. 2007) (court takes judicial notice of SEC filings for motion to dismiss); *U.S. ex rel. Lam v. Tenet Healthcare Corp.*, 481 F.

Supp. 2d 673, 680 (W.D. Tex. 2006) (in FCA action, court takes judicial notice of publicly available financial reports), *aff'd*, 287 Fed. Appx. 396 (5th Cir. 2008) (copy attached as Exhibit 1).

Likewise, when considering a motion to dismiss for failure to state a claim under Rule 12(b)(6), the Court may look outside the pleadings to take judicial notice of matters in the public domain. *See Norris v. Hearst Trust*, 500 F.3d 454, 461 n. 9 (5th Cir. 2007), *citing Cinel v. Connick*, 15 F.3d 1338, 1343 n. 6 (5th Cir. 1994); *In re Unicapital Corp. Sec. Lit.*, 149 F. Supp. 2d 1353, 1358 n. 2 (S.D. Fla. 2001). The Court also may consider exhibits attached to the complaint, and if an allegation is contradicted by exhibits to the complaint, the exhibit supersedes the allegation in the complaint. *See U.S. ex rel. Riley v. St. Luke's Episcopal Hospital*, 355 F.3d 370, 377 (5th Cir. 2004), *citing Simmons v. Peavy-Welsh Lumber Co.*, 113 F.2d 812, 813 (5th Cir.), *cert. denied*, 311 U.S. 685 (1940).

In addition, when considering a Rule 12(b)(6) motion, the Court is only required to assume (and only for purposes of the motion) the truth of well-pled factual allegations; a court does *not* assume the truth of conclusory factual allegations or assertions of law in a complaint. *See Fernandez-Montes v. Allied Pilots Ass'n*, 987 F.2d 278, 284 (5th Cir. 1993); *Jones v. Enterprise Rent A Car Co. of Texas*, 187 F. Supp. 2d 670, 674 (S.D. Tex. 2002) (“conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss”), *quoting Fernandez-Montes*, 987 F.2d at 284; *Northern Trust Co. v. Peters*, 69 F.3d 123, 129 (7th Cir. 1995); *In re CNET Networks*, 483 F. Supp. 2d at 953. Moreover, a court should not assume the truth of factual allegations when those allegations are contradicted by judicially noticed facts. *Blackburn v. Fisk Univ.*, 443 F.2d 121, 123 (6th Cir. 1971).

A plaintiff alleging fraud must plead with particularity. Fed. R. Civ. P. 9(b). Fifth Circuit courts have interpreted the heightened pleading requirements of Rule 9(b) to require, at a minimum “that a plaintiff set forth the ‘who, what, when, where, and how’ of the alleged fraud.” *U.S. ex rel. Williams v. Bell Helicopter Textron, Inc.*, 417 F.3d 450, 453 (5th Cir. 2005). Causes of action arising under the FCA are fraud claims that must be pled with particularity in accordance with Rule 9(b). *U.S. ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 328 (5th Cir. 2003), *citing U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). Likewise, in federal courts, claims arising under state law false claims statutes must satisfy Rule 9(b). *See Williams v. WMX Technologies, Inc.* 112 F.3d 175, 177 (5th Cir. 1997) (applying Rule 9(b) requirements to allegations of fraud under state law); *see also U.S. ex rel. Foster v. Bristol-Myers Squibb Co.*, __ F. Supp. 2d __, 2008 WL 4360697 at *21 (E.D. Tex. Sept. 24, 2008) (copy attached as Exhibit 2) (applying Rule 9(b) in the context of claims filed under state versions of the FCA).

The foregoing standards are not merely boilerplate principles routinely included in a motion to dismiss. The pleading standards discussed above, when applied to the particular allegations in Steury’s First Amended Complaint, are critical to demonstrating why her First Amended Complaint fails as a matter of law and must be dismissed.

III. SUMMARY OF ALLEGATIONS IN COMPLAINT

Steury alleges that she was employed as an account consultant for Alaris Medical Systems, Inc. (“Alaris”) between March 18, 1996 and September 28, 2001. “Plaintiff’s First Amended Complaint Pursuant to 31 U.S.C. § 3729-3732, Federal False Claims Act and Various

State False Claims Act” (hereinafter “Complaint”) ¶ 2.² According to Steury, Alaris sold the “Signature Edition Infusion Device,” referred to as the “SE infusion pump” in the Complaint. *Id.* Steury alleges that the SE infusion pump was designed to deliver a variety of fluids to patients. *Id.* ¶ 4. Alaris began to sell the SE infusion pumps in 1996. *Id.* ¶ 3. Steury alleges that on or about June 28, 2004, “Cardinal Health acquired Alaris and continued to market and sell these devices under the brand name Alaris until August 28, 2006.” *Id.* Steury refers to all defendants, as well as alleged predecessor-in-interest, Alaris, collectively as “Cardinal Health.” Complaint (“Parties” section) ¶¶ 1-5.

Moreover, Steury alleges that the design of the SE infusion pumps allowed air bubbles to move through tubing that carried intravenous fluids to patients. *Id.* ¶¶ 5-8. Steury asserts that the presence of air bubbles constituted a “dangerous defect.” *Id.* ¶ 2. The SE infusion pumps were equipped with an “air-in-line detector” which was designed to alarm if air bubbles passed into the tubing carrying fluids to patients. *Id.* ¶ 9. According to Steury, the air-in-line detector was “fallible.” *Id.* *The Complaint reveals, however, that Steury learned of the alleged defect indirectly from others.*

Steury asserts that she learned of the alleged defect in the SE infusion pump in 2000, while she was assigned by Alaris to assist with the implementation of the SE infusion pumps at Children’s Hospital Medical Center of Akron (“CHMCA”). *Id.* ¶ 11. Steury learned of the alleged defect when Dr. Mark DiLuciano, a Pediatric Anesthesiologist at CHMCA, complained to Susan Springman (another Alaris employee) and Springman requested Steury to contact Dr. DiLuciano. *Id.* ¶¶ 12-13. Dr. DiLuciano allegedly told Steury that “Alaris was withholding

² The Complaint contains six numbered paragraphs under the headings of “Parties” and “Jurisdiction and Venue,” and then begins numbering paragraphs again in the section titled “Introduction.” Unless otherwise indicated, all references herein to specific paragraph numbers in the Complaint refer to the numbering sequence as commenced in the “Introduction” section on page 4 of the Complaint.

information about the air-in-line problem.” *Id.* ¶ 13. Steury also asserts that “[a]fter speaking with Dr. DiLuciano’s assistant, David Bastock, Steury learned about Dr. DiLuciano’s complaint....” *Id.* ¶ 13. In addition, various unnamed employees at CHMCA “voiced their complaints regarding the air-in-line problem....” *Id.* ¶ 14. Further, Steury alleges that Tim Vanderveen, Alaris’s Director of Medication Management Systems, “drew a diagram to explain to the others how the design defect [in] the SE infusion pumps caused air to enter into the intravenous line and into the patient.” *Id.* ¶ 16.

Steury alleges that the purported defect in the SE infusion pump posed “serious health dangers, including death and serious injury.” *Id.* ¶ 22. Steury alleges that Kim Bergert, one of the nurses at CHMCA, told Steury that an infant had died at the hospital, allegedly “after an air bubble had entered the child’s intravenous line from the SE infusion pump.” *Id.* ¶ 14. The Complaint does not identify any other patient – either at CHMCA or any other hospital – who purportedly was injured by the SE infusion pump. According to Steury, however, “Cardinal Health continued manufacturing, selling and allowing the product to remain in use, even after it knew that the SE infusion pump’s defect had actually killed patients.” *Id.* ¶ 23.

Steury asserts that on unspecified dates, unnamed persons at “Cardinal Health”³ made representations to other unnamed persons “that the SE infusion pump would automatically sound an alarm if air entered the line, but it knew that the air-in-line detector often failed to detect air traveling through the intravenous tubing towards the patient.” *Id.* ¶ 24. Moreover, Steury asserts that on unspecified dates, unnamed persons at “Cardinal Health” fraudulently concealed from other unnamed persons “the existence of the defect in the SE infusion pump by failing to report

³ Steury’s Complaint uses the shorthand, “Cardinal Health,” to refer to the three named defendants, as well as their alleged predecessor-in-interest, Alaris. Complaint (“Parties” section) ¶ 5.

an incident involving the death of an infant to the FDA” and by “[telling] hospitals it was working on the defect and it had suspended sales, when in fact it had done neither.” *Id.* ¶¶ 25-26.

Thus, Steury’s Complaint acknowledges that the alleged “defect” in the SE infusion pump was disclosed by “Cardinal Health.” *Id.* ¶ 26. *Steury’s allegation of “fraud” collapses to the contention that “Cardinal Health” had represented that it was working to fix the alleged “defect” in the SE infusion pumps, but purportedly was not working to fix it. Id.*

Steury attached several emails as exhibits to her Complaint indicating that – contrary to the assertion of an alleged “defect” – *the “air-in-line” problem related to improper use of the SE infusion pumps by CHMCA’s staff.* For example, in an email dated June 8, 2001, from Marianne Gill at Alaris to CHMCA, Gill instructed: “Make sure the blood filters are completely primed with blood or saline during the infusion. This will greatly reduce the air bubbles during infusion.” *See Exhibit A to Complaint, at ALAR 1738-1740.* Gill also instructed: “As we discussed, using add-on buretrols cause a loss of prime in the drip chamber, which results in air-in-line alarms....You may want to consider transitioning away from the ECD. This would prevent many of the air-in-line alarms that occur from the loss of prime scenario.” *Id.* Another email dated August 24, 2001, notes that “Air-in-line alarms approx. 3-4 hours after infusion has been running. Many solutions are placed in refrigerator therefore causing outgassing to occur....Pump did not alarm with infiltrate.” *Id.* at ALAR 1814.

Nonetheless, Steury asserts that on unspecified dates, unnamed persons at “Cardinal Health” fraudulently induced unnamed agencies of the “Government” and unnamed “private purchasers” to buy the SE infusion pump by allegedly misrepresenting and concealing unspecified information regarding the pump’s alleged “defect.” Complaint ¶¶ 28-32.

The Complaint contains allegations conceding the FDA’s regulatory oversight of medical devices. *Id.* ¶¶ 33-41. The Complaint also contains allegations regarding the Medicare, Medicaid and TriCare/CHAMPUS health care programs that pay hospitals for providing services to program beneficiaries. *Id.* ¶¶ 42-44.⁴ Steury asserts that “Cardinal Health” defrauded the government by selling allegedly “defective” infusion pumps: (1) directly to Veterans Administration (“VA”) hospitals, and (2) indirectly to private hospitals, which in turn allegedly billed the Medicare, Medicaid and TriCare/CHAMPUS programs for using the pumps. *Id.* ¶ 1.

Significantly, the Complaint fails to include undisputed facts in the public record, of which the Court may take judicial notice. Specifically, consistent with the FDA’s acknowledged regulatory oversight (Complaint ¶¶ 33-41), several “Adverse Event Reports” were filed with the FDA several years *before* Steury commenced this action on May 11, 2007. *Those Adverse Event Reports specifically discussed the air-in-line and alarm issues associated with the SE infusion pump that Steury later mentioned in her Complaint.*

For example, an Adverse Event Report was filed with the FDA on September 3, 1997, regarding Alaris’s SE Infusion Pump, a copy of which is attached as Exhibit 3. That report noted air in the line, but following manufacturer testing, “[t]here was no fault found with the pump.” *Id.* The report was in the FDA’s public records nearly ten years before Steury filed her Complaint.

Another Adverse Event Report regarding Alaris’s SE infusion pump was filed with the FDA on June 4, 1999, a copy of which is attached as Exhibit 4. The report alleged that “air was noted in the line to the pt (patient) and the pump did not alarm.” Still another Adverse Event

⁴ Medicare is a federal health insurance program primarily for elderly beneficiaries. *See generally* 42 U.S.C. § 1395 *et seq.* Medicaid is a joint federal-state health insurance program primarily for low-income beneficiaries. *See generally* 42 U.S.C. § 1396 *et seq.* TriCare/CHAMPUS is a federal health insurance program for members of the armed forces. *See generally* 32 C.F.R. Part 199.

Report was filed with the FDA on January 14, 2000, regarding Alaris's SE Infusion Pump, a copy of which is attached as Exhibit 5. That report stated: "[i]t was alleged that air was noted in the line below the pump's detector and no alarm." *Id.* Testing on the device by the manufacturer concluded that the "device met all mfr's spec. Co was unable to duplicate or confirm the reported event." *Id.* Those reports were in the FDA's public records before Steury is first alleged to have had involvement with the SE infusion pump (October 2000). Complaint ¶ 11.

Based on the foregoing allegations, and undisputed facts in the public domain, this Court may not properly exercise subject matter jurisdiction over Steury's Complaint. Furthermore, Steury cannot state a claim for relief under the FCA or parallel state law statutes. Accordingly, Steury's Complaint must be dismissed as a matter of law.

IV. ARGUMENT

A. **The Court Cannot Properly Exercise Subject Matter Jurisdiction Over the Federal and State FCA Claims Because Steury's Complaint is Based on Public Disclosures and Steury is Not an "Original Source"**

The FCA authorizes private parties to initiate a *qui tam* action on behalf of the Government. 31 U.S.C. § 3730(b). The Act "'promot[es] private citizen involvement in exposing fraud against the government,' while at the same time, 'prevent[s] parasitic suits by opportunistic late-comers who add nothing to the exposure of fraud.'" *U.S. ex rel. Fried v. West Independent School District*, 527 F. 3d 439, 441 (5th Cir. 2008), *citing U.S. ex rel. Reagan v. East Texas Med. Ctr.*, 384 F. 3d 168, 174 (5th Cir. 2004). Because of the opportunities for relators to receive substantial compensation under the Act, sometimes a relator files a "parasitic suit" seeking a reward even though she actually played no role in revealing the alleged fraud.

In an attempt to prevent these types of opportunistic suits, the FCA includes important limitations on the subject matter jurisdiction of courts over *qui tam* suits, including provisions that expressly deprive a court of jurisdiction over any *qui tam* action where the relator's

allegations of fraud are based on information that has been publicly disclosed, unless the relator is an “original source” of the information underlying the action. *Reagan*, 384 F.3d at 176.

Specifically, the FCA’s jurisdictional bar provides:

(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or [General] Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For the purposes of this paragraph, “original source” means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(A), (B).

The jurisdictional bar in the FCA reflects the intent of Congress to reward only a relator who, through a *qui tam* complaint, brings new information of fraud to the government’s attention. “The reason is that the allegations in the complaint, being previously undisclosed, are valuable to the government in remedying the fraud that is being committed against it.” *U.S. ex rel. Biddle v. Board of Trustees of the Leland Stanford, Jr. University*, 161 F.3d 533, 539 (9th Cir. 1998), *citing* H.R. Rep. No. 99-660, at 22 (1986). However, if the allegations of the complaint “do not benefit the government because the government already knew about them, then § 3730(e)(4)(A) bars jurisdiction” unless the relator is an original source of the information. *Id.*

In addition to invoking the federal False Claims Act, Steury also has brought claims under the false claims statutes of seventeen States and the District of Columbia. Each of these state law statutes contains a jurisdictional bar similar, if not identical, to the jurisdictional bar in

the federal statute.⁵ Thus, this Court cannot properly exercise subject matter jurisdiction over Steury's state law FCA claims for the same reasons that it lacks jurisdiction over Steury's federal FCA claim – because Steury's Complaint is based on a prior public disclosure and she is not an original source.

In the Fifth Circuit, the jurisdictional analysis under 31 U.S.C. § 3730(e)(4) is divided into three steps. First, the Court must determine whether, at the time a relator filed her complaint, there had been a “public disclosure” of the “allegations or transactions” and, second, whether the relator's complaint is “based upon” those publicly disclosed allegations. *See Reagan*, 384 F.3d at 173. Third, if the relator's complaint is based upon publicly disclosed allegations or transactions, the Court must determine if the relator is an “original source” of the information. *See id.*

Here, because numerous “Adverse Event Reports” were filed with the FDA and available on the FDA's website several years before Steury's lawsuit was filed, and those reports discuss the same alleged “defect” in the SE infusion pump that is at issue in Steury's Complaint, Steury's *qui tam* action is based upon allegations publicly disclosed in an administrative report and investigation. Further, Steury is not an original source of the information alleged in her Complaint because she does not have direct and independent knowledge of the information forming the basis of her allegations. Accordingly, the FCA's jurisdictional bar applies and this action must be dismissed as a matter of law.

⁵ Indeed, Steury pleads each of her state law claims in a manner that parrots her federal law claim. *See* Complaint ¶ 79, *citing* Cal. Gov't Code § 12652(d)(3); ¶ 89, *citing* 6 Del. § 1206(c); ¶ 99, *citing* D.C. Code § 2-308.15(c)(2); ¶ 109, *citing* Fla. Stat. § 68.087(3); ¶ 119, *citing* Haw. Rev. Stat. § 661-28; ¶ 129, *citing* 740 ILCS 175/4(e)(4); ¶ 139, *citing* Ind. Code § 5-11-5.5-7(t); ¶ 149, *citing* La. Rev. Stat. Ann. § 46:439.1(E); ¶ 159, *citing* Mass. Gen. Laws 12 § 5G; ¶ 169, *citing* Mich. Comp. L. § 400.610a(13); ¶ 179, *citing* Mont. Code Ann. § 17-8-403(5)(c); ¶ 189, *citing* N.R.S. § 357.100; ¶ 199, *citing* N.H. Rev. Stat. Ann. § 167:61-e(III)(d); ¶ 209, *citing* N.M. Stat. Ann. § 27-14-10(C); ¶ 219, *citing* NY Bill S02108 [codified at N.Y. State Finance Law § 190(9)]; ¶ 229, *citing* Tenn. Code Ann. § 71-5-183(e)(2); ¶ 239, *citing* V.T.C.A. Hum. Res. Code § 36.113(b); ¶ 249, *citing* Va. Code § 8.01-216.8.

1. The Allegations in the Complaint have been Publicly Disclosed

Under 31 U.S.C. § 3730(e)(4), the jurisdictional bar applies in cases where allegations have been disclosed in a “criminal, civil, or administrative hearing...a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or...the news media.” The “touchstone of public disclosure is potential accessibility by those who are not a party to the fraud.” *Lam*, 481 F. Supp. 2d at 681. It is not necessary for information to be widely disseminated in order to constitute a “public disclosure” under the FCA; the statute merely requires that there be sufficient information in the public domain to expose the allegation at issue. *Id.*

In this case, Steury’s allegation of an alleged “defect” in the SE infusion pump was publicly disclosed on the FDA’s website several times *before* Steury commenced this action on May 11, 2007. For example, an Adverse Event Report was filed with the FDA on September 3, 1997, alleging an air-in-line problem with Alaris’s SE Infusion Pump (Exhibit 3). Another Adverse Event Report regarding Alaris’s SE infusion pump was filed with the FDA on June 4, 1999, alleging that “air was noted in the line to the pt (patient) and the pump did not alarm” (Exhibit 4). Later, an Adverse Event Report was filed with the FDA on January 14, 2000, regarding Alaris’s SE Infusion Pump, in which “[i]t was alleged that air was noted in the line below the pump’s detector and no alarm” (Exhibit 5). The Adverse Event Reports publicly disclose the same “defect” alleged by Steury: the alleged failure of the SE infusion pump’s alarm to detect air in the line.

The FDA’s Adverse Event Reports undoubtedly constitute a “public disclosure” within the meaning of 31 U.S.C. § 3730(e)(4)(A). In *Fried*, the Fifth Circuit found that publication of allegations on a federal agency’s website or “reporting portal” constitutes public disclosure for purposes of the FCA’s jurisdictional bar. *Fried*, 527 F.3d at 442 (matter posted in General

Accounting Office's "FraudNET" system related to "the very essence of the allegations made by Fried"). The court found that publication of the allegations in "trade publications and on the internet," further supported its conclusion that the allegations had been publicly disclosed within the meaning of 31 U.S.C. § 3730(e)(4)(A). *Id.*

Likewise, in *Lam*, a Texas federal court ruled that publication of allegations in trade journals and Internet news sites constituted "public disclosures" for purposes of 31 U.S.C. § 3730(e)(4)(A). *Lam*, 481 F. Supp.2d at 683. The District Court focused on allegations referenced in the "Weakley Report," published by UBS Warburg's Global Equity Research, that provided customers with economic forecasts and investment strategies. The court found that the Weakley Report:

...is analogous to both a newspaper article and a magazine article. It is like a newspaper in that it reports on newsworthy aspects of investment. It is like a magazine article in that UBS publishes these type of reports on a semi-regular basis to its customers...like a newspaper and magazine article, its existence and coverage are both generally known and capable of accurate determination by resort to sources whose accuracy cannot reasonably be questioned.

Lam, 481 F. Supp. 2d at 680. Accordingly, the court took judicial notice of the Weakley Report, concluding that the Report was "potentially accessible by those not a party to the fraud...[and] the information was publicly disclosed prior to [the date] when Relators filed their complaint." *Id.* at 682.

Similarly, here, the Adverse Event Reports discussed above, regarding the same alleged "defect" in the SE infusion pump that Steury asserts in her Complaint, were publicly disclosed on the FDA's Internet website in connection with the FDA's medical device reporting system. "Medical Device Reporting (MDR) is the mechanism for the Food and Drug Administration to receive significant medical device adverse events from manufacturers, importers and user facilities, so they can be detected and corrected quickly." *See* "Medical Device Reporting

(MDR) – General Information” (copy attached as Exhibit 6), available at www.fda.gov/cdrh/mdr/mdr-general.html. The Adverse Event Reports are posted on the Internet for the express purpose of informing the public of alleged problems with medical devices. Thus, there was a “public disclosure of allegations,” within the meaning of 31 U.S.C. § 3730(e)(4)(A), with respect to the alleged air-in-line and failure-to-alarm issues associated with the SE infusion pump.

2. Steury’s Complaint is Based Upon the Publicly Disclosed Allegations

The next prong in the FCA’s “public disclosure” analysis is whether a relator’s complaint is “based upon” a public disclosure. *Reagan*, 384 F.3d at 173. A relator’s complaint is based upon public disclosures if the allegations in the complaint are substantially similar to those that have been disclosed prior to the filing of the complaint. *Lam*, 481 F. Supp.2d at 683. It is not necessary to prove that a relator’s allegations were actually derived from publicly-disclosed information. *See id.* (“A *qui tam* action is based upon public disclosures if it repeats what the public already knows, regardless of whether or not Relators learned about the fraud independent of the public disclosures”), citing *U.S. ex rel. Findley v. FPC-Boron Employees’ Club*, 105 F.3d 675, 683 (D.C. Cir. 1997). Here, the allegations in Steury’s Complaint so closely mirror the information published in the FDA Adverse Event Reports that there is no doubt her Complaint is based upon those prior public disclosures.

Steury asserts that the “SE infusion pumps manifested a serious defect by allowing air to enter an intravenous line and to pass into the intravenous line going into a patient,” and further asserts that the “air-in-line detector often failed to detect air traveling through the intravenous tubing towards the patient.” Complaint ¶¶ 21, 24. However, as discussed above, Adverse Event Reports filed with the FDA (as early as ten years before Steury’s Complaint) addressed the *same* issues with respect to the *same* medical device. Steury’s allegations do not need to mirror

perfectly the information contained in the Adverse Event Reports, nor does Cardinal need to “prove” that Steury’s allegations were actually derived from the Adverse Event Reports or based solely on those reports. It is sufficient that Steury’s allegations are “substantially similar” to allegations that were previously disclosed to the public through the FDA’s Adverse Event Reports. *See Reagan*, 384 F.3d at 173; *Fried*, 527 F.3d at 442; *Federal Recovery Services, Inc. v. U.S.*, 72 F.3d 447, 451 (5th Cir. 1995); *Lam*, 481 F. Supp. 2d at 683. Thus, this Court cannot properly exercise subject matter jurisdiction, unless Steury qualifies as “an original source of the information.” 31 U.S.C. § 3730(e)(4)(A).

3. Steury is Not an Original Source

To qualify as an “original source” under 31 U.S.C. § 3730(e)(4)(B), the relator must be able to show: (1) that she had “direct and independent” knowledge of the information upon which her allegation is based, and (2) that she voluntarily provided the information to the government before filing her *qui tam* action. *Reagan*, 384 F.3d at 177. The original source standard requires a relator to have both direct *and* independent knowledge of the information that forms the basis of her claim. *Fried*, 527 F.3d at 442. Here, because Steury has neither “direct” nor “independent” knowledge of the allegations made in her Complaint, she does not qualify as an original source under the FCA.

“Direct knowledge” means that the information was derived by the relator’s own efforts rather than learned second-hand. *Reagan*, 384 F.3d at 177; *Lam*, 287 Fed. Appx. at 400. “Independent knowledge” means that the information was not derived from a public disclosure. *Reagan*, 384 F.3d at 177. In *Reagan*, the Fifth Circuit concluded that “Reagan’s extensive investigation did not put the government ‘on the trail’ of any new malfeasance; it only led her to re-tread the same ground that [the government] had already covered....” *Id.* at 179. “When a relator’s claim is based on knowledge received from other persons it is not direct and

independent.” *Lam*, 287 Fed. Appx. at 400-01. “Relators found to have direct and independent knowledge are those who actually viewed source documents or viewed firsthand the fraudulent activity that is the basis for their qui tam suit.” *Id.* at 400.

Here, Steury’s own Complaint demonstrates that her allegations are based on second-hand information that was given to her by employees of Children’s Hospital of Akron. For example:

- “...Dr. Mark DiLuciano...complained to Springman....*Dr. DiLuciano discovered* that they were having the same problem with the SE infusion pumps.” Complaint ¶ 12 (emphasis added);
- “...[A]fter speaking with Dr. DiLuciano’s assistant, David Bastock, Steury *learned* about Dr. DiLuciano’s complaint and *information he gathered* from the other hospitals regarding the defect.” Complaint ¶ 13 (emphasis added);
- “...Steury *learned* of the death of an infant...when...Kim Bergert, a nurse at Children’s Hospital of Akron, pulled her aside at a meeting...*Kim Bergert...told Steury* that she had watched a baby die after an air bubble had entered the child’s intravenous line.” Complaint ¶ 14 (emphasis added).

Steury’s Complaint also refers to unspecified “Children’s Hospital of Akron nurses and employees [who] voiced their complaints regarding the air-in-line problem.” Complaint ¶ 14. Steury’s Complaint, however, is devoid of any allegation that she learned any pertinent facts firsthand. The information that Steury purportedly learned about the SE infusion pumps came *indirectly* from doctors, nurses or other employees at the hospital.

Nor is there any basis to infer that Steury could have direct and independent knowledge of allegedly false claims related to the SE infusion pump. Steury alleges that she was employed by Alaris as a “temporary sales support person.” Complaint ¶ 11. She does not allege that she has any knowledge, training or experience as a doctor, nurse, or medical device technician that could provide her with a basis to develop direct and independent knowledge regarding the alleged “defect” in the SE infusion pump. Furthermore, she does not allege that she ever saw the

SE infusion pump being used on any patient. Moreover, she does not allege that she was involved in submitting payment claims for the SE infusion pump to any government agency. Rather, Steury derived her allegations secondhand by overhearing the “complaints” of hospital staff regarding the performance of the SE infusion pump. *See* Complaint ¶¶ 12-14; *Lam*, 287 Fed. Appx. at 401 (rejecting relator as original source where information derived indirectly from hospital staff).

Here, the issues raised by Steury’s Complaint (including the exhibits thereto), *e.g.*, infusion pumps that purportedly allow air into intravenous lines, the alarm system built into the pump, the alleged design flaw, the errors by hospital staff, and the alleged risk to patients, involve medical and engineering issues outside the scope of Steury’s job function, training and experience. In addition, Steury asserts that her first involvement with the SE infusion pump was in October 2000. Complaint at ¶ 11. However, prior to October 2000, there were Adverse Event Reports filed with the FDA regarding the same alleged “defect” that Steury asserts in her Complaint. *See* Exhibits 3-5. Thus, the asserted “defect” in the SE infusion pump had been publicly disclosed long before Steury had any involvement with the medical device. Steury seeks an undeserved bounty for repeating information that had been previously disclosed without any contribution from Steury. Clearly, Steury lacks “direct and independent” knowledge of the alleged “defect” and, therefore, cannot qualify as an “original source” of the allegations in her Complaint.

Steury bears the burden of establishing that this Court has subject matter jurisdiction; she cannot rest on the allegations in the Complaint (which, in any event, reveal that Steury is not an original source). *See Williamson*, 645 F.2d at 413; *Morris*, 540 F. Supp. at 900-01. The allegations in the Complaint, along with the undisputed facts, of which this Court may take

judicial notice, demonstrate that Steury's federal and state FCA claims are barred by the FCA's jurisdictional bar. Moreover, this defect cannot be cured through an amendment to the Complaint; any attempt to amend the Complaint would be futile. *See U.S. ex rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375, 387 (5th Cir. 2003) (Fifth Circuit upholds denial of leave to amend FCA complaint); *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 569 (6th Cir. 2003) (denying leave to amend complaint in FCA action where amendment would be futile); *Foster*, 2008 WL 4360697 at *24 (denying leave to amend FCA complaint where defects in complaint are "incurable"), *citing Hart v. Bayer Corp.*, 199 F.3d 239, 248 n. 6 (5th Cir. 2000). Consequently, this action must be dismissed with prejudice.

B. The Federal and State FCA Claims Must Be Dismissed Because the Alleged Claims Relating to Infusion Pumps Were Not Knowingly False

The FCA creates liability for a person who, *inter alia*:

- (1) knowingly presents, or causes to be presented to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
- (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; [or]
- (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a). As defined by the FCA, a person acts "knowingly" if the person has actual knowledge that a claim is false, acts with "deliberate ignorance" as to the truth or falsity of a claim, or acts in "reckless disregard" as to the truth or falsity of a claim. 31 U.S.C. § 3729(b).

"[T]he statute's definition of 'knowingly' excludes liability for innocent mistakes or negligence." *U.S. v. Southland Management Corp.*, 326 F.3d 669, 681 (5th Cir. 2003).

Likewise, the Fifth Circuit has rejected the premise that there can be FCA liability based on “‘mere’ contractual or regulatory non-compliance.” *Id.* at 681-82. “[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations. The FCA is a fraud prevention statute; violations of [agency] regulations are not fraud unless the violator knowingly lies to the government about them.” *Id.* at 682, *quoting U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1019 (7th Cir. 1999); *Willard*, 336 F.3d at 381 (“The False Claims Act does not create liability merely for a health care provider’s disregard of Government regulations...unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe”). In other words, the FCA is intended to reach lies made to the government, not mere errors. *U.S. ex rel. Riley v. St. Luke’s Episcopal Hospital*, 355 F.3d 370, 376 (5th Cir. 2004) (“the FCA requires a statement known to be false, which means a lie is actionable but not an error”).

Here, Steury has failed to allege a knowingly false claim and, therefore, has failed to state a claim under any of the foregoing provisions of the FCA that she cites in her Complaint.

1. The Alleged “Defect” in the SE Infusion Pump Does Not Constitute a Knowingly False Claim

The foundation of Steury’s Complaint is that the alarm contained within the SE infusion pump, designed to detect air bubbles in an intravenous line, did not function properly.

The SE infusion pumps are equipped with an air-in-line detector, which alerts a healthcare professional to the presence of an air bubble in the fluid....The air-in-line detector is the final effort to detect the air bubble in the fluid before entering the patient. This feature is fallible, however, and often still allows air bubbles to pass to the patient.

Complaint ¶ 9. The gist of Steury’s fraud theory is that Cardinal “told hospitals it was working on the defect and it had suspended sales, when in fact it had done neither.” *Id.* ¶ 26.

Even assuming *arguendo* that the pump’s alarm system was “fallible” as Steury alleges, a medical device that falls short of perfect performance does not equate to a violation of the FCA. Steury does not allege that Cardinal represented the SE infusion pump to be “infallible” while knowing that the device was “fallible.” To the contrary, the Complaint alleges that the SE infusion pumps were equipped with an alarm precisely because the device sometimes allowed air bubbles into intravenous fluids. *Id.* ¶ 9. Moreover, the Complaint precludes any inference that hospitals purchasing the SE infusion pump expected “perfect” performance from the pump because Steury alleges that Cardinal “told hospitals it was working on the defect....” *Id.* ¶ 26.

Indeed, an FDA regulation specifically recognizes that infusion pumps are subject to “fault” conditions, *e.g.*, allowing air bubbles in an intravenous line, and that alarms may be used to detect such air bubbles. 21 C.F.R. § 880.5725 (“The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm”). Thus, the FDA itself does not establish a standard of perfect performance for infusion pumps. *See Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir.) (“Perhaps Luckey could persuade the Food and Drug Administration to require more or different testing; but when a supplier complies with the existing regulations, it is entitled to represent to the government (and the world) that it has done so, without facing a claim of deception”), *cert. denied*, 528 U.S. 1038 (1999). There is no colorable basis to assert that Cardinal made a knowingly false claim regarding the “infallibility” of the SE infusion pump when Steury’s Complaint acknowledges that Cardinal “told hospitals it was working on the defect” [Complaint ¶ 26] and, at bottom, Steury’s grievance is that Cardinal did not correct the alleged “defect.” *Id.*⁶

⁶ While elsewhere in the Complaint Steury asserts that Cardinal made “affirmative misstatements and material omissions regarding the safety, reliability, quality and performance of the SE infusion pumps” [*e.g.*, Complaint ¶ 28], such conclusory assertions - without supporting factual allegations, and contradicted by Steury’s more detailed

Even assuming *arguendo* that Cardinal did not correct the alleged “defect” in the SE infusion pump – an allegation contradicted by the FDA’s public records showing no defect whatsoever and Steury’s exhibits showing misuse of the pump by hospital staff – that allegation does not state a claim for “fraud.” Steury’s assertion that the SE infusion pump was “fallible” amounts to nothing more than an asserted breach of a sales agreement between Cardinal and a hospital that purchased the SE infusion pump, or an asserted violation of the FDA’s medical device standards. However, the FCA is not a remedy for breach of contract or violation of regulatory requirements. *Riley*, 355 F.3d at 376; *Willard*, 336 F.3d at 381; *Southland*, 326 F.3d at 681-82; *U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003); *Lamers*, 168 F.3d at 1019; *see also U.S. ex rel. Conner v. Salina Reg. Health Center, Inc.*, 543 F.3d 1211, 1219 (10th Cir. 2008) (rejecting FCA false certification claim where regulation “does not contain language stating that payment is conditioned on *perfect* compliance with any particular law or regulation”) (emphasis added).

As Steury recognizes in her Complaint, there are comprehensive administrative enforcement mechanisms already in place to address allegedly defective medical devices.

- “[m]edical device manufacturers are subject to mandatory and stringent controls over product design, manufacture, process changes, rework, specifications, specification changes, and quality control.” Complaint ¶ 33;
- “Federal regulations provide applicable manufacturing standards for medical devices shipped and sold in the United States...” Complaint ¶ 34;
- “Medical device manufacturers are, among other things, required to establish and maintain procedures to control the design of a medical device to ensure the finished device conforms to approved design...” Complaint ¶ 35;

allegation that Cardinal disclosed the defect [Complaint ¶ 26] – should not be relied upon by Steury to salvage her claims. *See U.S. ex rel. Wilkins v. N. Am. Const. Corp.*, 173 F. Supp. 2d 601, 617 (S.D. Tex. 2001) (“the court need not accept as true ‘conclusory’ allegations or allegations of inferences that are contradicted by the facts pleaded or set out in the exhibits attached to or incorporated in the pleading”).

- “Medical device manufacturers are also subject to mandatory reporting obligations to the FDA...” Complaint ¶ 39;
- “Federal law requires that device manufacturers take full responsibility for product recalls, and to assure that recalls are successful. FDA guidelines classify medical device recalls by the severity of the potential consequences.” Complaint ¶ 41.

Apart from the allegations in the Complaint, a review of the Code of Federal Regulations reveals that the FDA has adopted comprehensive regulations concerning the pre-approval of medical devices (such as infusion pumps) before they are marketed to the public, the monitoring of those devices in the marketplace, and the corrective action to be taken in the event of a defective device.

For example, the FDA oversees the pre-market approval of medical devices. *See* 21 C.F.R. Part 814. The purpose of those regulations is to approve medical devices “that have been shown to be safe and effective” and to disapprove devices “that have not been shown to be safe and effective.” 21 C.F.R. § 814.2. The FDA utilizes a pre-market approval process involving, *inter alia*, an advisory committee. 21 C.F.R. § 814.44. The FDA may disapprove the medical device if a manufacturer’s application for approval “contains a false statement of material fact” or if the manufacturer does not permit the FDA a full opportunity to inspect the device. 21 C.F.R. § 814.45(a)(1), (3). In addition, the FDA may withdraw its prior approval of a medical device and, in such a case, affords an administrative hearing to review its decision. 21 C.F.R. § 814.46.

Furthermore, the FDA has adopted medical device tracking requirements. *See* 21 C.F.R. Part 821. “These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices... is necessary for the effectiveness of remedies prescribed by the [Federal Food, Drug, and Cosmetic] Act, such as patient notification...or device recall...” 21

C.F.R. § 821.1(b). The FDA is authorized to recall medical devices [21 C.F.R. § 810.13], or to order manufacturers to cease distribution of medical devices if the FDA “finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death....” 21 C.F.R. § 810.10(a).

Moreover, FDA regulations establish reporting requirements for medical device manufacturers. 21 C.F.R. § 803.50. The FDA oversees “Medical Device Reporting.” As described by the FDA, “Medical Device Reporting (MDR) is the mechanism for the Food and Drug Administration to receive significant medical device adverse events from manufacturers, importers and user facilities, so they can be detected and corrected quickly.” See “Medical Device Reporting (MDR) – General Information” (Exhibit 6), available at www.fda.gov/cdrh/mdr/mdr-general.html.

In sum, the FDA has full regulatory authority over all aspects of medical devices, including without limitation, pre-market approval, device tracking, and device recalls. Moreover, the FDA has the requisite expertise regarding the enforcement of standards for medical devices. Of particular interest for this litigation, the FDA has authority to regulate a manufacturer’s false statements regarding a medical device. 21 C.F.R. § 814.45(a)(1). Thus, a *qui tam* action under the FCA is the wrong forum to adjudicate whether a medical device is defective.

Courts have not allowed FCA actions to proceed when they involve regulatory matters suited to the specialized expertise of an administrative agency. For example, in *Conner*, the Tenth Circuit found that a provider’s allegedly false certification of compliance with Medicare regulations did not state a cause of action under the FCA because, *inter alia*, the Government already has a “complex monitoring and remedial scheme.” *Conner*, 543 F.3d at 1222.

As the Second Circuit has cautioned, “courts are not the best forum to resolve medical issues concerning levels of care.” [*citing U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 700 (2nd Cir. 2001)] It is therefore with good reason that the agencies of the federal government, rather than the courts, manage Medicare participation

in the first instance in cooperation with the states and accreditation organizations. *See id.* (“[P]ermitting qui tam plaintiffs to assert that defendants’ quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government would replace the aggrieved patient as the plaintiff.”) And when an individual plaintiff is harmed, state tort law remains a powerful incentive for hospitals to provide quality care. There is thus no basis in either law or logic to adopt an express false certification theory that turns *every* violation of a Medicare regulation into the subject of an FCA qui tam suit.

Conner, 543 F.3d at 1221 (emphasis in original).

The Fifth Circuit has likewise held that the FCA is not the appropriate remedy for alleged violations of regulations. In *Southland*, where the government filed an FCA action against owners of an apartment complex claiming that they falsely certified compliance with HUD housing standards, the Fifth Circuit found that “the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations.” *Southland*, 326 F.3d at 682. *See also U.S. ex. rel. Windsor v. DynCorp, Inc.*, 895 F. Supp. 844, 852 (E.D. Va. 1995) (in FCA action based on Labor Department’s complex labor classification, court recognized “wisdom in requiring classification disputes to be resolved in the administrative arena”).

The Medicare participation standards at issue in *Conner*, the HUD housing standards at issue in *Southland*, and the DOL labor classification standards in *DynCorp* are similar to the FDA medical device standards raised by Steury’s Complaint: they should be resolved by the administrative agency with the requisite expertise. As in *Conner*, *Southland* and *DynCorp*, where the alleged dispute was a regulatory compliance matter better suited to the expertise of an administrative agency, here Steury’s FCA action should be dismissed because her claim is founded on an alleged “defect” in a complex medical device and, to the extent there needs to be any further resolution of that issue – beyond the Adverse Event Report process already utilized – the matter should be addressed through the FDA’s administrative enforcement system.

2. The Submission of Adverse Event Reports to the FDA Regarding the SE Infusion Pump Negates Any Inference That Cardinal Submitted Knowingly False Claims

As alleged in the Complaint, manufacturers of medical devices are subject to FDA regulations, including a reporting obligation to the FDA when an issue arises regarding a medical device. Complaint ¶ 39. The FDA's administrative oversight is not merely an abstract concept; in reality, the FDA's administrative process is effective and already has addressed the alleged "defect" in the SE infusion pump at issue in this action.

More specifically, the FDA maintains publicly-available information concerning medical devices through its searchable "Medical and User Facility Device Experience Database" ("MAUDE") that is accessible through the FDA's Internet website.⁷ Included in the MAUDE database are "Adverse Event Reports" regarding medical devices. As early as 1997, the FDA had received and published an Adverse Event Report regarding the "air-in-line" issue with the SE infusion pump. *See* Exhibit 3. As early as 1999, the FDA had received and published Adverse Event Reports regarding the alleged failure of the pump's alarm system that detects air in an intravenous line. *See* Exhibits 4-5. Alaris investigated those incidents and, following inspections, reported to the FDA that there were no defects in the devices. *Id.*

While Steury may not accept the conclusion that the SE infusion pumps functioned properly, she cannot dispute the fact that the FDA was aware of the alleged air-in-line and alarm failure issues, and that Alaris submitted reports to the FDA regarding those issues. The Adverse Event Reports were posted on the FDA's website, available to the public at large, as well as to

⁷ As described by the FDA, "MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996." *See* "Manufacturer and User Facility Device Experience Database (MAUDE)" (copy attached hereto as Exhibit 7), available at www.fda.gov/cdrh/MAUDE.html.

the Veterans Administration, the Medicare program, the TriCare/CHAMPUS program, and any state Medicaid program. The fact that Alaris submitted information to the FDA regarding the alleged air-in-line and alarm failure issues, which information was published and available to the entire world vis-à-vis the Internet negates as a matter of law any possibility that Alaris, or Cardinal (as its alleged successor-in-interest), could have knowingly concealed the alleged “defect” in the SE infusion pump.

In *Southland*, the Fifth Circuit sustained the dismissal of an FCA claim brought against property owners participating in a HUD housing program. The owners had allegedly submitted false certifications that their property was “decent, safe and sanitary.” *Southland*, 326 F.3d at 674-76. The court, however, concluded that based on information in HUD’s possession, and the agency’s decision to pay the owners despite HUD’s knowledge of the property’s condition, the defendants could not have submitted knowingly false claims. *Id.* at 682-83.

HUD was aware that [the] project was deteriorating for several years preceding its foreclosure. The types of problems emphasized by the government as creating substandard living conditions were not hidden defects....The record reflects at most the give and take between the owners and HUD over the priority of various repairs, but it does not cast doubt on the owners’ investment of every penny of subsidy in the project. As the district court noted, HUD’s policy of approving continued subsidy payments notwithstanding the project’s declining condition was based not on its ignorance of the true condition but upon the imperative to provide housing for the tenants while HUD supervised the use of the limited funds it allocated to the project.

Id. at 683-84. See *U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (“[T]he government’s knowledge of the facts underlying an allegedly false record or statement can negate the scienter for an FCA violation”); *U.S. ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 328 (9th Cir. 1995) (Army’s awareness of discrepancy in testing procedure for equipment precluded knowingly false claim); *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) (“The fact that the government knew of FMC’s mistakes and limitations,

and that FMC was open with the government about them, suggests that while FMC might have been groping for solutions, it was not cheating the government in the effort”).

In the instant case, information about the alleged air-in-line and failure-to-alarm “defect” in the SE infusion pump was reported to the FDA and posted on the FDA’s website in the form of Adverse Event Reports. Moreover, those reports indicate that Alaris cooperated with the FDA to investigate alleged performance issues regarding the SE infusion pumps. The Adverse Event Reports were available to the entire world, including the VA and private hospitals that allegedly purchased the SE infusion pump. Furthermore, the Adverse Event Reports were available to any federal or state health insurance program that allegedly paid a private hospital that had used the pump for its patients. *See U.S. ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 953-54 (10th Cir. 2008) (Defense Department’s access to Department of Energy data provided government with knowledge regarding accuracy of defendant’s claim and precluded defendant from submitting knowingly false claim). The Adverse Event Reports directly contradict, and thereby supersede, Steury’s allegations that Cardinal failed to submit adverse event reports and “fraudulently concealed a “defect” in the SE infusion pump. *See* Complaint ¶¶ 25, 29; *Riley*, 355 F.3d at 377.

While the government’s knowledge does not automatically preclude an FCA claim in all cases, in this particular case the Adverse Event Reports to the FDA, together with the broad public dissemination of those documents on the Internet, negate any inference that Cardinal could have knowingly concealed the alleged “defect” that already had been disclosed to the world vis-à-vis the FDA’s Internet website. Thus, Steury has failed to state a claim under the federal or state FCAs. *Southland*, 326 F.3d at 683-84; *Burlbaw*, 548 F.3d at 953-54; *Becker*, 305 F.3d at 289; *Butler*, 71 F.3d at 328; *Wang*, 975 F.2d at 1421.

C. Steury Has Failed to Satisfy the Essential Elements for a Violation of the FCA

Steury's Complaint fails to plead the essential elements of the asserted FCA violations. *See* Complaint ¶ 64, *quoting* 31 U.S.C. § 3729(a)(1), (2), (3) and (7).

1. Cardinal Did Not Present a False Claim for Payment to a Federal Agency

The FCA creates liability for knowingly presenting a false claim for payment to a federal agency. *See* 31 U.S.C. § 3729(a)(1). In order to state a claim under that provision of the FCA, at a minimum Steury must allege that a knowingly false claim was submitted to a federal agency for payment. "It is not enough for "a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government....some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government." *Clausen*, 290 F.3d at 1311; *see U.S. ex rel. Aflatooni v. Kitsap Physicians Service*, 314 F.3d 995, 1002-03 (9th Cir. 2002); *Foster*, 2008 WL 4360697 at * 6.

Steury, however, has failed to meet the most fundamental and essential prerequisite of alleging a knowingly false claim for payment presented to a federal agency. Steury's Complaint focuses almost exclusively on alleged events at Children's Hospital Medical Center of Akron (CHMCA). Steury does not allege that CHMCA is a federally-owned Veterans Administration hospital and there is no reasonable basis to draw such an inference. Steury refers to a single VA hospital by name – "Veterans Administration Hospital of Ohio" (Complaint ¶ 19) – but she does not assert that a false claim was presented to that VA hospital and there is no reason to infer that Steury would have any basis to make such an assertion. Steury alleges that she was assigned to

assist with sales of the SE infusion pump at CHMCA. *Id.* ¶ 11. However, Steury does not allege that she was assigned to handle sales of the pump at any VA hospital.

Steury asserts that “Cardinal Health must expressly certify compliance with the federal Government’s standards for reliability, quality, and approved-specifications for each SE pump that it delivered.” Complaint ¶ 56. That conclusory assertion must be rejected, especially because it is made “on information and belief,” yet the alleged certification requirements are not exclusively within Cardinal’s knowledge, nor does Steury’s Complaint provide any factual predicate for her information and belief. *See U.S. ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 308 (5th Cir. 1999) (relator pleading on information and belief must allege factual basis for information and belief, and defendant must have exclusive knowledge of facts). Steury’s assertion regarding the certification requirements applicable to an unspecified government agency is conclusory and relates to a matter of law; therefore, the allegation that Cardinal made a false express certification is not assumed to be true for purposes of the instant motion. *See Willard*, 336 F.3d at 379; *Fernandez-Montes*, 987 F.2d at 284.

Steury’s Complaint also fails to assert a false “implied certification” to VA hospitals that may have purchased SE infusion pumps. Under the implied certification theory, a defendant may be deemed to have certified its compliance with applicable laws, in the absence of an express certification, when the defendant receives payment from the government and payment is conditioned on regulatory compliance. *See Willard*, 336 F.3d at 382. The Fifth Circuit has not adopted the implied certification theory as a basis for liability under the FCA. *See U.S. ex rel. Marcy v. Rowan Companies, Inc.*, 520 F.3d 384, 389 (5th Cir. 2008); *Willard*, 336 F.3d at 381. However, even if the implied certification theory applied in this Circuit, an implied certification could be found only if the government *conditioned payment* on compliance with a particular law.

Willard, 336 F.3d at 382; *U.S. ex rel. Graves v. ITT Educational Services, Inc.*, 284 F. Supp. 2d 487, 501-02 (S.D. Tex. 2003), *aff'd*, 111 Fed. Appx. 296 (5th Cir. 2004), *cert. denied*, 544 U.S. 978 (2005).

Steury's Complaint does not assert that any payment made by the Veterans Administration for SE infusion pumps was *conditioned* on Cardinal's compliance with any particular law. The Complaint asserts that "[b]y accepting payment from the federal Government or one of its agencies for the SE infusion pumps, Cardinal Health knowingly misrepresented that the SE infusion pumps were safe, reliable and quality-assured." Complaint ¶ 52. That allegation, however, makes no reference to the Veterans Administration and clearly falls short of asserting that any payment by the VA was conditioned on Cardinal's compliance with any particular statute or regulation.

The Federal Acquisition Regulations (FARs) applicable to government contractors indicate that "the Government may require the Contractor to replace or correct any supplies that are nonconforming...." 48 C.F.R. § 52.246-3(f). That regulation affords the government remedies other than denial of payment to the contractor, *e.g.*, correction of the defect and termination of the contract for default. 48 C.F.R. § 52.246-3(g). Moreover, that regulation also provides that in the event of the contractor's fraud, lack of good faith, or willful misconduct, the government may require the contractor to correct or replace nonconforming supplies. 48 C.F.R. § 52.246-3(h). Thus, even in the case of a contractor's fraud regarding the performance of a medical device, the Government would not necessarily withhold payment.

Because government payment may be made despite a medical device's defects - and despite a contractor's alleged fraud with respect to the performance of that device - even assuming *arguendo* the existence of the alleged "defect" and alleged "fraud" asserted by Steury,

payment by the VA for the purchase of a medical device is not conditioned on the device satisfying particular standards imposed by law. Thus, as a matter of law, there could be no false “implied certification” in this case. *Willard*, 336 F.3d at 382; *Graves*, 284 F. Supp. 2d at 501-02.

Apart from the theory of implied certification, the Fifth Circuit requires an alleged false claim to be “material” in order to be actionable under the FCA. *See Marcy*, 520 F.3d at 389; *Wilkins*, 173 F. Supp. 2d at 624. “A material claim is one that is required to be made in order to receive the relevant government benefit.” *Marcy*, 520 F.3d at 389-90 (relator fails to state FCA claim because claim not material to obtaining government benefit). Based on the FARs discussed above, it is clear that the government’s decision to pay for a medical device does not depend on the device being free of any defect. The government has administrative remedies, other than denial of payment, to correct non-conforming goods. Thus, Steury’s FCA claim, to the extent it is based on the sale of “defective” medical devices to VA hospitals, fails to satisfy the materiality requirement for an actionable FCA violation. Accordingly, the Complaint fails as a matter of law and must be dismissed.

2. Cardinal Did Not “Cause” the Submission of False Claims to the Medicare, Medicaid or TriCare/CHAMPUS Programs

In addition to creating liability for knowingly presenting a false claim for payment to a federal agency, the FCA creates liability for knowingly “causing” a third party to submit a false claim for payment to a federal agency. *See* 31 U.S.C. § 3729(a)(1).

As Steury concedes in her Complaint, Cardinal never submitted claims for payment directly to Medicare, Medicaid, or TriCare/CHAMPUS; instead, Cardinal allegedly sold SE infusion pumps to private hospitals and those hospitals, in turn, allegedly submitted false claims to those health insurance programs. *See* Complaint ¶¶ 1, 53, 57, 60. Thus, any potential FCA liability must rest on an allegation that Cardinal knowingly caused private hospitals to submit

false or fraudulent claims to Medicare, Medicaid or the TriCare/CHAMPUS programs. However, Steury fails to meet the standard for alleging that a defendant knowingly “caused” a third party to submit a false claim.

i. Cardinal Had No Active Role In Hospitals’ Submission of Claims to Health Insurance Programs

The FCA requires affirmative action on the part of a defendant in the process of submitting a payment claim before liability may be imposed; mere knowledge of the falsity of those claims is not sufficient to establish liability under the Act. *U.S. ex rel. Sikkenga v. Regence Blue Cross Blue Shield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006), citing *U.S. v. Bornstein*, 423 U.S. 303, 396 (1976). Thus, § 3729(a)(1) requires “some action by the defendant whereby the claim is presented or caused to be submitted.” *U.S. ex rel. Camillo v. Ancilla Systems, Inc.*, 2005 WL 1669833 *3 (S.D. Ill. Jul. 18, 2005) (copy attached as Exhibit 8); see also *U.S. ex rel. Tillson v. Lockheed Martin, Corp.*, 2004 WL 2403114 *33 (W.D. Ky. Sept. 30, 2004) (copy attached as Exhibit 9); *U.S. v. President and Fellows of Harvard College*, 323 F.Supp.2d. 151, 186 (D. Mass. 2004); *U.S. ex rel. Grynberg v. Ernst & Young*, 323 F.Supp.2d 1152, 1155 (D. Wy. 2004).

Here, Steury fails to assert that Cardinal was even aware that hospitals were submitting payment claims for the pumps to federal and state health insurance programs, let alone assert that Cardinal had an active role in the hospitals’ alleged submission of such claims to those programs. Because Cardinal had no affirmative role in private hospitals’ alleged submission of payment claims to the Medicare, Medicaid and TriCare/CHAMPUS programs for SE infusion pumps, as a matter of law Cardinal could not knowingly cause the submission of false claims. Therefore, Steury’s claim under the FCA for “causing” false claims must be dismissed.

ii. The Performance of the SE Infusion Pumps Was Not Material to the Federal and State Health Insurance Programs' Decisions to Make Payments to Hospitals

The Fifth Circuit requires an alleged false claim to be “material” in order to be actionable under the FCA. *See Marcy*, 520 F.3d at 389; *Wilkins*, 173 F. Supp. 2d at 624. “A material claim is one that is required to be made in order to receive the relevant government benefit.” *Marcy*, 520 F.3d at 389-90 (relator fails to state FCA claim because claim not material to obtaining government benefit). Here, Steury’s FCA claim fails for a lack of materiality.

The Medicare program does not rely on itemized bills to determine how much Medicare pays a hospital generally, and specifically does not rely on itemized bills to determine how much a hospital will be paid for infusion pumps used to provide services to hospitals patients. Instead, since 1983, as Steury herself recognizes, hospitals have been paid by Medicare under a “Prospective Payment System (“PPS”), whereby hospitals would receive *fixed diagnosis-based payments* for each patient that reflected the average costs an efficient provider would be expected to incur in treating such a patient” (emphasis added). Complaint ¶ 44; *see also* 42 U.S.C. § 1395ww *et seq.* (outlining Medicare’s PPS methodology). Likewise, all of the state Medicaid programs identified in the Complaint, as well as the CHAMPUS/TriCare program, use a prospective payment system.⁸

⁸ The PPS reimbursement methodology pioneered by Medicare has served as the model for the other federal and state health care programs referenced in the Complaint, including CHAMPUS/TriCare and the state Medicaid programs mentioned in Steury’s Complaint. *See* Complaint ¶¶ 1, 42-43. The PPS-based reimbursement methodology used by the CHAMPUS/TriCare program is described generally at 32 C.F.R. § 199.14. A PPS-based reimbursement methodology is used by the state Medicaid programs at issue in this case. *See* Cal. Welf. & Inst. Code § 14084(a); 40-850-001 Del. Code Regs § 1.13.1; D.C. Mun. Regs. tit. 29 § 4800; Fla. Stat. § 409.908; Haw. Code R. § 17-1739-55; Ill. Admin. Code Tit. 89 § 140.2; 405 Ind. Admin. Code § 1-10.5-3; La. SPA, Attachment 4.19-A; 114.1 Mass. Code Regs. § 36.05; Mich. SPA, Attachment 4.19-A; Montana Admin. R. §§ 37.86.2805; Nev. SPA, Attachment 4.19-A; N.M. Code R. § 8.311.3.10; 10 NYCRR 86-1.60; Tenn. Comp. R & Regs. 1200-13-5-.06; 1 Tex. Admin. Code §355.8052; 12 Va. Admin. Code §30-70-50.

In *U.S. ex rel. DiGiovanni v. St. Joseph's/Candler Health System, Inc.*, 2008 WL 395012 (S.D. Ga. Feb. 8, 2008) (copy attached as Exhibit 10), a relator filed an FCA action asserting that a hospital had submitted false claims to Medicare requesting payment for medical supplies and equipment. The court considered whether the relator's claim satisfied the materiality requirement of the FCA. *Id.* at *5 & n. 5, citing *Southland*, 326 F.3d at 679 and *Wilkins*, 173 F. Supp. 2d at 624. The *DiGiovanni* court concluded that the PPS system utilized to pay the hospital precluded an FCA claim due to the lack of materiality.

Because the *PPS system pays a standard rate* based on the patient diagnosis and the [federally determined Diagnosis Related Group, or] DRG code, the itemized charges on a patient's bill are *immaterial* to the amount of reimbursement a provider receives from Medicare Part A. Accordingly, even if the Relator proves that St. Joseph's/Candler was improperly including charges for reusable equipment in claims submitted to Medicare, this improper submission of claims would have no effect on the amount of reimbursement. The alleged improper practices would therefore not be material, under any standard, to the claims submitted to the government. Further, the improper claims would not result in, or contribute to, any loss to the public fisc.

For this reason, the allegations in the Complaint fail to state a claim that Defendant submitted materially false or fraudulent claims for payment....

Id. at * 6 (emphasis added).

Steury's assertion that alleged false claims were submitted by private hospitals to federal and state health insurance programs, such as Medicare, is substantially similar to the claim rejected in *DiGiovanni*. Contrary to the Steury's allegations in Paragraph 45 of the Complaint, the amount of money a hospital receives depends *solely* on each patient's particular diagnosis and other clinical information, *not* on medical devices listed on an itemized bill sent to the program. A hospital does not receive one penny more or less from the government if the hospital uses an infusion pump that works perfectly or a pump that fails to work as intended.

For the time period at issue in the Complaint, *i.e.*, post-1983, hospitals have been paid by the federal and state health care programs as follows. The federal Medicare program assigns

each patient discharge to one of approximately 500 Diagnosis-Related Groups (“DRGs”) “based on essential data abstracted from the inpatient bill for that discharge.” 42 C.F.R. § 412.60(c). The regulations are clear that “each discharge is assigned to only one DRG (related ... to the patient’s principal diagnosis) regardless of the number of conditions treated or services furnished during the patient’s stay.” 42 C.F.R. § 412.60(c)(2). Thus, the assignment of a DRG to a patient’s hospital stay is *not affected at all* by the type of equipment used to provide services, the number of pieces of equipment used to provide services, or even whether the equipment used by the hospital to provide services functioned well.

Hospitals are required to accept that *pre-determined* reimbursement rate calculated for the specific DRG as “payment in full” for *all* the operating and capital costs the hospital incurs to provide services to the patient while she is in the hospital, including medical devices. 42 C.F.R. § 412.2(b); Medicare Hospital Manual, CMS Pub. 10, Section 210.4 (copy attached as Exhibit 11).⁹ “[I]temized costs on a [hospital] claim do not affect the amount [a federal program] reimburses a provider” under PPS. *DiGiovanni*, 2008 WL 395012 at * 6, *citing* 42 C.F.R. §412.2(f). Consequently, payment claims submitted to the federal and state health insurance programs – even if they include medical devices such as infusion pumps – are immaterial to the government payment. *See DiGiovanni*, 2008 WL 395012 at * 6. Accordingly, Steury fails to state a claim that Cardinal knowingly caused hospitals to submit false claims to federal and state health insurance programs. *Id.*; *Marcy*, 520 F.3d at 389; *Wilkins*, 173 F. Supp. 2d at 624.

⁹ Effective January 1, 2006, Section 210.4 was re-designated as Section 40 of the Medicare Benefit Policy Manual.

iii. Cardinal Did Not Cause Hospitals to Make False Certifications to the Federal and State Health Care Programs

Steury alleges – without any supporting citation, and only on information and belief - that “by selling defective products to healthcare providers participating in federal and state funded health insurance programs, Cardinal Health caused [hospitals] to falsely certify that the SE infusion pumps were medically necessary.” Complaint ¶ 57. In addition, Steury asserts that “Cardinal Health caused [hospitals] to falsely certify that the SE infusion pumps met governmental standards and were safe and reliable.” *Id.* ¶ 60. Such conclusory assertions regarding matters of law are not assumed to be true for purposes of this motion to dismiss. *See Riley*, 355 F.3d at 377; *Willard*, 336 F.3d at 379. Moreover, Steury’s assertions reflect a fundamental misunderstanding of the certification process used by the federal and state health insurance programs at issue.

To the extent Steury asserts a false express certification, neither the Medicare program nor any state Medicaid program or the TriCare/CHAMPUS program requires an express certification regarding the performance of infusion pumps as a condition of payment to the hospital for services furnished to inpatients, and none of these programs conditions payment to hospitals on the quality of infusion pumps used to provide services to patients. *See Willard*, 336 F.3d at 382; *Graves*, 284 F. Supp. 2d at 501-02; *U.S. ex rel. Bailey v. Ector County Hospital*, 386 F. Supp. 2d 759, 764 (W.D. Tex. 2004) (“as the Fifth Circuit previously recognized, under either implied or express certification theories, the certification must be a prerequisite to receive the government benefit in order to be legally false”).

Hospitals file annual cost reports with the Medicare program that include the following certification provision:¹⁰

PART I – CERTIFICATION			
Check applicable box	<input type="checkbox"/> Electronically filed cost report	Date: _____	Time: _____
	<input type="checkbox"/> Manually submitted cost report		

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WHERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

CERTIFICATION BY OFFICER OR ADMINISTRATOR OF PROVIDER(S)

I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ (Provider Names(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and that to the best of my knowledge and belief, it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

(Signed) _____

Officer or Administrator of Provider(s)

Title

Date

It is obvious from a cursory review of the foregoing Medicare certification that hospitals make no express certification regarding the performance of infusion pumps. Thus, Steury's allegation regarding a false express certification to the federal and state health insurance programs must fail as a matter of law.

Further, as a matter of law there could be no false implied certification regarding the reliability, quality or safety of the SE infusion pump because payment by federal and state health insurance programs to hospitals that used the SE infusion pump was not conditioned on the performance of that device. *See Willard*, 336 F.3d at 382; *Graves*, 284 F. Supp. 2d at 501-02. As discussed above, those programs paid hospitals under a PPS system. The regulations at 42 C.F.R. §§ 412.40 – 412.52 set out the "Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs. The government

¹⁰ The certification is excerpted from Medicare's "Hospital and Hospital Health Care Complex Cost Report" (Form 2552-96), available at www.cms.hhs.gov/Manuals/PBM.

relies only on the following conditions when making the decision to pay a hospital for services furnished: (1) a finding that the hospital made no charge to a government beneficiary for any service payable by Medicare, Medicaid or any governmental program “even if the hospital’s costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment systems” [42 C.F.R. § 412.42(a)]; (2) documentation that the hospital conducts ongoing reviews of the “medical necessity, reasonableness and appropriateness of hospital admissions and discharges” and the services furnished [42 C.F.R. § 412.44(a)]; and (3) documentation of physician acknowledgments that “payment under the prospective payment system is based in part on each patient’s principal and secondary diagnoses and major procedures performed, as evidenced by the physician’s entries in the patient’s medical record.” [42 C.F.R. § 412.46(a)]. Thus, the pertinent regulations do *not* condition payment to a hospital based on the hospital’s use of medical equipment that is safe, reliable or not defective.

To the extent a hospital makes any certification at all related to the performance of medical equipment, it is limited to the provision of *services* involving medical equipment that has FDA approval. *See* 42 C.F.R. § 405.201(a)(1) (“CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions”). The SE infusion pumps were, in fact, approved by the FDA. *See* FDA Notice, dated Mar. 25, 2005 (copy attached as Exhibit 12).¹¹ Under federal law, hospitals that use the FDA-approved infusion pumps satisfy the condition for payment for services furnished using that FDA-approved medical device. Steury does not allege that Cardinal or the hospitals using the SE infusion pump made a false

¹¹ The Court may take judicial notice of the FDA notice, which is publicly accessible on the FDA’s website, available at www.fda.gov/cdrh/pdf4/K043590.pdf. The FDA concluded that Cardinal’s SE infusion pump is “substantially equivalent...to legally marketed predicate devices.” (The infusion pump had previously been marketed by Alaris.) The FDA advised Cardinal that “You may, therefore, market the device, subject to the general controls provisions of the Act.”

certification regarding the FDA's approval of the pump. In sum, there is no basis for Steury's assertion of law that hospitals "impliedly certify" that the SE infusion pumps are safe, reliable and non-defective [Complaint ¶¶ 57-60] because payment by the federal and state health insurance programs is not conditioned on the medical devices satisfying those criteria.¹² See *DiGiovanni*, 2008 WL 395012 at *6; *Willard*, 336 F.3d at 382; *Graves*, 284 F. Supp. 2d at 501-02. Thus, Steury's claim must be dismissed.¹³

3. Cardinal Did Not Make or Use a False Record

The FCA makes it unlawful for a person knowingly to make or use a false record to get a false claim paid by the Government. 31 U.S.C. § 3729(a)(2). Here, the Complaint fails to identify, or even generally describe, any particular "false record" made or used by Cardinal to get a false claim paid. Moreover, a defendant must do more than make a false record; the defendant "must have the purpose of getting a false or fraudulent claim 'paid or approved by the Government' in order to be liable under § 3729(a)(2)." *Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 128 S. Ct. 2123, 2128 (2008). The Complaint fails to allege that Cardinal made or used a false record with the purpose of getting the government to pay a false claim. See *id.* The Complaint rests on the cursory assertion that Cardinal created "fraudulent records." Complaint ¶

1. On a motion to dismiss, that sparse allegation is *not* assumed to be true. See *Fernandez-*

¹² Indeed, one of the Medicare policy manuals explains that even if a hospital receives money back from a manufacturer related to a product that turns out to be defective, "payments to a hospital for inpatient services under the prospective payment system (PPS) are not reduced to reflect collections under warranty provisions for [these defective] medical devices." Medicare Benefit Policy Manual (CMS Pub. 100-02), §40.4 - Items Covered Under Warranty, copy attached as Exhibit 13.

¹³ Steury's claim is distinguishable from an FCA claim asserted in *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998). In *Thompson*, the relator alleged that a health care provider's payment claims to Medicare violated the FCA because the provider had falsely certified compliance with the "Anti-Kickback Law" and the "Stark Law" and Medicare payment was conditioned on compliance with those laws. In this case, Steury does not allege that Cardinal's payment claims were false based on non-compliance with the Anti-Kickback Law or the Stark Law. Here, unlike *Thompson*, payment was *not* conditioned on compliance with a particular statute or regulation.

Montes, 987 F.2d at 284. In short, Steury has failed to state a claim for relief under 31 U.S.C. § 3729(a)(2).

4. There Can Be No FCA Conspiracy Claim Because the Alleged Misconduct Does Not Involve Multiple Parties

The FCA creates liability for conspiring to defraud the federal government by getting a false claim paid. 31 U.S.C. § 3729(a)(3). A conspiracy requires the participation of two or more parties. *Graves*, 284 F. Supp. 2d at 509; *Reagan Regional Healthcare System*, 274 F. Supp. 2d 824, 856-57 (S.D. Tex. 2003), *aff'd*, 384 F.3d 168 (5th Cir. 2004). For purposes of a conspiracy claim, parent and subsidiary corporations are treated as a single entity. *Reagan*, 274 F. Supp. 2d at 856.

Here, Steury alleges that the SE infusion pumps were first introduced and sold by Alaris. Complaint ¶ 3. During that time, Alaris was the lone entity allegedly selling the SE infusion pump and, therefore, could not have been involved in a conspiracy. Following the alleged acquisition of Alaris by “Cardinal Health” on or about June 28, 2004, Cardinal Health allegedly sold the device thereafter until August 28, 2006. *Id.* The entity that Steury refers to as “Cardinal Health” [Complaint (“Parties” section) ¶ 5] is a group of related corporate entities that is deemed by operation of law to constitute a single entity unable to conspire with itself. Thus, at no time were two or more entities involved in the sale of the SE infusion pump. Consequently, there could be no FCA conspiracy with regard to the SE infusion pump and Steury’s claim under 31 U.S.C. § 3729(a)(3) must be dismissed as a matter of law.

5. There Can Be No “Reverse” False Claim Because There Was No Fixed Obligation to Repay the Government at the Time the Alleged False Claims Were Made

The FCA creates liability for knowingly making or using a false record to avoid the repayment of an obligation to the federal government. 31 U.S.C. § 3729(a)(7). This is

commonly known as the “reverse false claim” provision. *See U.S. ex rel. Bain v. Georgia Gulf Corp.*, 386 F.3d 648, 653 (5th Cir. 2004). A reverse false claim results only when the defendant has an established obligation to repay the federal government at the time a false record is made or used. *Id.* at 657 (“the reverse false claims act does not extend to the potential or contingent obligations to pay the government”). It is not enough to allege that the defendant had a potential liability to the government when a false record is made or used. *Id.*

Here, Steury has not made any factual allegation that Cardinal had an established obligation to return any funds to the government at the time Cardinal allegedly made or used a false record or statement, or that Cardinal knowingly made or used a false record in order to avoid an obligation to repay the government. Indeed, the Complaint contains no factual allegations at all in support of a reverse false claim, but merely cites to the relevant provision of the FCA. *See* Complaint ¶ 64 (iv).

Steury asserts that Cardinal “fraudulently induced” the government’s purchase of SE infusion pumps [Complaint ¶ 28], *i.e.*, the alleged false claim would have been made *before* any particular pump was delivered and determined to be defective. Steury does not allege that all pumps were defective. *See* Complaint ¶ 24. At the time any alleged false record would have been made by Cardinal, there would have been nothing more than a *potential* liability to repay the government for an allegedly defective infusion pump, but that is insufficient to state a reverse false claim. *Bain*, 386 F.3d at 657. Furthermore, Cardinal could not have an obligation to return payments to the Medicare, Medicaid or TriCare/CHAMPUS programs because, as Steury acknowledges [Complaint ¶ 1], Cardinal did not submit any claims for payment to those programs. Accordingly, Cardinal could not have received payment from the programs and, necessarily, could not have any obligation to return funds to those programs.

In short, Steury has failed to state a reverse false claim. Consequently, her claim under 31 U.S.C. § 3729(a)(7) must be dismissed as a matter of law.

D. Steury's Complaint Fails to Plead the Federal and State FCA Claims with Particularity Pursuant to Rule 9(b)

Complaints alleging violations of the federal and state FCA statutes must satisfy Rule 9(b)'s heightened pleading requirements. *Doe*, 343 F.3d at 328; *Williams*, 112 F.3d at 177; *Foster*, 2008 WL 4360697 at *21; *Wilkins*, 173 F. Supp. 2d at 614. The Fifth Circuit has interpreted Rule 9(b) to require, at a minimum "that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud." *Williams*, 112 F.3d at 453. In the case of claims brought under the FCA, Rule 9(b) requires the relator to set forth the "time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby." *Doe*, 343 F.3d at 329. The relator also must specify how the alleged conduct of the defendant is fraudulent. *See Williams*, 112 F.3d at 179.

In most cases, a relator cannot satisfy the particularity requirement of Rule 9(b) by pleading fraud on the basis of information and belief. *See Russell*, 193 F.3d at 308; *Foster*, 2008 WL 4360697 at *12. The Fifth Circuit has recognized a narrow exception to the Rule 9(b) particularity standard if "the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge." *Russell*, 193 F.3d at 308. However, a plaintiff who enjoys the advantage of this relaxed pleading standard is nonetheless required to set forth the factual basis for her "information and belief." *Id.* Moreover, the exception "must not be mistaken for a license to base claims of fraud on speculation and conclusory allegations." *Thompson*, 125 F.3d at 903 (internal quotations omitted). In the Fifth Circuit it is necessary that a plaintiff satisfy Rule 9(b)'s heightened pleading requirement prior to being granted access to the discovery process. *Russell*, 193 F.3d at 308-09 ("A special relaxing of Rule 9(b) is a *qui tam* plaintiff's

ticket to the discovery process that the statute itself does not contemplate”); *Williams*, 112 F.3d at 179; *Tuchman v. DSC Comm. Corp.*, 14 F.3d 1061, 1067 (5th Cir. 1994).

Here, Steury’s Complaint clearly fails to satisfy Rule 9(b). Steury’s failure to plead alleged false claims with particularity is not surprising, given that she does not have the direct and independent knowledge of alleged false claims required of an original source under the FCA. Her lack of direct and independent knowledge prevents her from specifying the “who, what, when, where, and how” of the alleged fraud that is essential to satisfy Rule 9(b). *See Williams*, 417 F.3d at 453.

1. The Complaint Fails to Identify Who was Involved in the Alleged False Claims

Steury fails to specify which person(s) at Cardinal allegedly made knowingly false claims. Indeed, the Complaint even fails to identify which corporate defendant or combination of defendants allegedly submitted false claims. The Complaint names three corporate defendants and alludes to another entity, Alaris, as defendants’ purported predecessor-in-interest. Complaint (“Parties” section ¶¶ 2-4.) The Complaint also defines the three defendants under the umbrella term “Cardinal Health.” Complaint (“Parties” section) ¶ 5. Steury then alleges that “Cardinal Health knowingly manufactured, sold, and allowed to remain in use thousands of defective” devices. *Id.* ¶ 20. The Complaint, however, fails to identify any employee at any entity who was allegedly involved in the submission of knowingly false claims. *See Williams*, 417 F.3d at 454.

Steury identifies employees at Alaris who purportedly knew the SE infusion pump had an alleged “defect” [Complaint ¶¶ 15-19], but she does not assert that any of those employees submitted an alleged false claim to a government entity. Thus, the Complaint fails to satisfy Rule 9(b) because it does not specify the person(s) who allegedly submitted or caused the submission of knowingly false claims. *Doe*, 343 F.3d at 329.

2. The Complaint Fails to Identify What False Claims Are At Issue

With regard to the “what” component of a false claim, the Complaint does not identify even a single claim submitted to a government entity that allegedly was knowingly false. Instead, the Complaint merely asserts that “Cardinal Health fraudulently induced the Government and private purchasers to buy its defective product....” Complaint ¶ 28. The problem for Steury in this case is her own allegation that the alleged “defect” is that the alarm on the SE infusion pump “often” failed to detect air bubbles. Complaint ¶ 24. Thus, one cannot infer that every pump was defective because Steury herself alleges that only some of the pumps, on some occasions, had the alleged “defect.” *See id.* Thus, it is critical to identify which particular pumps were allegedly defective and on what occasions. *See Yuhasz*, 341 F.3d at 564-65 (FCA claim dismissed for failure to satisfy Rule 9(b) where relator alleged that payment claims for “certain” products were “often” false, but failed to specify particular invoices submitted to government that were allegedly false).

Although Steury’s Complaint is not required to provide a complete inventory of every alleged false claim, Steury utterly fails to identify even one false claim for payment submitted to a government entity. *See Yuhasz*, 341 F.3d at 564 (relator fails to satisfy Rule 9(b) where he is “unable to identify a specific claim submitted directly to the United States”). “[T]he fundamental element of an alleged FCA violation is a false or fraudulent claim that is submitted to the government.” *Foster*, 2008 WL 4360697 at * 6. The Complaint does not identify any particular occasion on which a federally-owned hospital purchased an SE infusion pump based on Cardinal’s alleged submission of a claim that was knowingly false.

Moreover, the Complaint does not identify any particular payment claim submitted to the Medicare, Medicaid or TriCare/CHAMPUS programs that allegedly was knowingly false and allegedly was knowingly “caused” by Cardinal. According to Steury, such payment claims were

submitted by private hospitals, not by Cardinal. Complaint ¶ 1. Those payment claims may be known to the hospitals that purportedly submitted them, and to the government programs that purportedly received them, but they are not within Cardinal's knowledge. Thus, Steury is not entitled to a relaxed pleading standard. *See Russell*, 193 F.3d at 308.

3. The Complaint Fails to Specify How Payment Claims Related to the Infusion Pumps were Allegedly False

Steury's Complaint also fails to specify how the alleged payment claims for the SE infusion pump were allegedly false. The Complaint asserts generally that Cardinal made false certifications regarding the SE infusion pump, but that conclusory assertion fails to satisfy the Rule 9(b) pleading standard. *See Willard*, 336 F.3d at 383. Steury does not specify how the asserted conduct of Cardinal is allegedly fraudulent. *See Wilkins*, 173 F. Supp. 2d at 642.

The Complaint does not describe with any specificity the certifications purportedly required by federal or state governments. Steury has not specified any provision in a contract between Cardinal and any government entity, or in any other document, in which Cardinal allegedly made an express certification regarding the performance of the SE infusion pumps. *See Willard*, 336 F.3d at 383 (rejecting relator's false certification claim under FCA based on relator's failure to identify contract provision that expressly conditioned payment on compliance with statute or regulation).

Instead, Steury alleges "upon information and belief, Cardinal Health must expressly certify compliance with the federal Government's standards for reliability, quality, and approved-specifications for each SE infusion pump it delivered." Complaint ¶ 56. Certainly, the government's standards for medical devices are not within the peculiar knowledge of Cardinal. Indeed, an FDA regulation discusses standards for infusion pumps. *See* 21 C.F.R. § 880.5725. In addition, Steury does not state the basis for her belief respecting purported express

certifications made to the government regarding the SE infusion pump. Consequently, Steury cannot plead “on information and belief” the existence of allegedly false express certifications regarding the SE infusion pump. *See Russell*, 193 F.3d at 308.

Steury fares no better in her attempt to allege a false “implied certification.” Steury does not specify any statute or regulation that conditioned payment on the performance of the SE infusion pump. The Complaint merely asserts, “upon information and belief,” that federal and state health insurance programs condition payment for medical devices on the device being “medical necessary,” as well as being “safe, reliable and quality-tested.” Complaint ¶¶ 57, 59-60. However, the conditions of payment required by federal and state health insurance programs certainly are not within the peculiar knowledge of Cardinal. That is publicly available information. Moreover, the Complaint does not even identify the basis for Steury’s information and belief. Hence, Steury’s allegations regarding allegedly false implied certifications to the government cannot be made on “information and belief.” *See Russell*, 193 F.3d at 308.

In sum, Steury has failed to plead her claims with the particularity required under Rule 9(b). Accordingly, Steury’s Complaint must be dismissed.¹⁴

E. Steury Has Failed to State a Claim Under the Common Fund Doctrine

In Count XX of the Complaint, Steury asserts that she is entitled to payment under the “common fund doctrine.” Steury has improperly invoked that doctrine; it has no application to this litigation.

¹⁴ While a dismissal under Rule 9(b) is often accompanied by leave to amend the complaint, in this case leave to amend should be denied because any amendment of Steury’s Complaint would be futile. *See Willard*, 336 F.3d at 387 (Fifth Circuit upholds denial of leave to amend FCA complaint); *Yuhasz*, 341 F.3d at 569 (denying leave to amend complaint in FCA action where amendment would be futile); *Foster*, 2008 WL 4360697 at *24 (denying leave to amend FCA complaint where defects in complaint are “incurable”), *citing Hart v. Bayer Corp.*, 199 F.3d 239, 248 n. 6 (5th Cir. 2000). As explained above, there are several fatal defects in Steury’s claims, including without limitation, the FCA’s jurisdictional bar and the absence of knowingly false claims.

The common fund doctrine has been applied in class action suits to prevent unjust enrichment of class members - who benefited from a recovery, but without sharing the expense of the litigation - “by assessing attorney’s fees against the entire fund, thus spreading fees proportionately among those benefited by the suit.” *See e.g. Boeing Co. v. Van Gemert*, 444 U.S. 472, 478 (1980). Hence, the common fund doctrine is a means to allocate attorneys’ fees equitably, *not* a substantive claim for relief that a plaintiff may assert against a defendant. *See id; Alyeska Pipeline Svc. Co. v. Wilderness Soc.*, 421 U.S. 240, 257 n. 30 (1975).

Here, all the plaintiffs in the instant case are federal and state governments represented by Steury, who has sued on their behalf under the federal and state FCA *qui tam* statutes cited in the Complaint. Because each of the governmental entities that Steury represents in this case has its own *qui tam* statute that permits Steury to share in any recovery she hopes to obtain on behalf of those entities, there is no possibility that any of the government-plaintiffs in this case will be “unjustly enriched” by Steury’s efforts in this litigation.

Moreover, Steury is limited to seeking her share of recovery according to the statutory schemes prescribed in the respective *qui tam* statutes on which her standing to sue is based. *See Equilease Corp. v. M/V Sampson*, 793 F.2d 598, 607 n. 11 (5th Cir.), *cert. denied*, 479 U.S. 984 (1986) (unjust enrichment is equitable remedy invoked only when there is no other available remedy). Thus, the common fund doctrine has no application to this litigation. Therefore, Count XX of the Complaint must be dismissed as a matter of law.

V. CONCLUSION

For the foregoing reasons, Cardinal's motion to dismiss should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of February, 2009, a true and correct copy of the foregoing document has been served on the following counsel of record through the Court's electronic case management system:

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